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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265

23115 7590 06/23/2006

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,429	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,23-26,28,29,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,23-26,28,29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/20/99;04/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20, 21, 23-26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. US 6,365,184, in view of Khankari et al. US 6,024,981.

Depui teaches an oral dosage form comprising proton pump inhibitor including lansoprazole (column 3, lines 54-67, and column 6). The proton pump inhibitor is in the form of pellet comprising a core and a coating layer (column 8, lines 29-39; column 9, lines 7-67). The coated pellet are mixed with inactive tablet excipients including L-HPC and compressed into tablet having disintegration time between 15-30 seconds (column

12, lines 35 through column 13, lines 1-64; and examples 2 and 5). Depui does not expressly teach the use of sugar in the solid mixture.

Khankari teaches a rapidly dissolving tablet comprising tablet excipients such as binder, and filler including sugar alcohol such as mannitol (see abstract; and column 9, lines 44-66). The amount of mannitol is disclosed in examples 4-8. The tablet disintegrated in the mouth in less than 45 seconds (column 11, lines 45-46; and column 15, lines 1-15). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Depui using mannitol in view of the teaching of Khankari, because Khankari teaches the tablet dissolves rapidly in the mouth of the patient with a minimum of grit (abstract), because Khankari teaches using mannitol as a tablet excipient to achieve superior compressibility, hardness, and rapid dissolution within the mount (column 10, lines 34-47), and because Depui teaches using tablet excipients and other pharmaceutically acceptable additives in combination with the coated pellet to compress into tablet (column 13, lines 51-55).

It is noted that Depui does not teach the percent substitution of the hydroxypropoxyl group. However, it is the position of the examiner that the L-HPC of Depui would have a similar percent substitution of the hydroxypropoxyl group because Depui teaches the use of L-HPC to obtain a similar fast disintegrating tablet dosage having disintegration time falls within the claimed range (see example 2).

Claims 20, 21, 23-26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al., in view of Khankari et al. US 6,024,981 and Makino et al. EP 0 553 777 A2.

Depui and Khankari are relied upon for the reason stated above. Depui does not expressly teach the percent substitution of a hydroxypropoxyl group in the L-HPC.

Makino teaches a composition comprising granules having a core coated with spraying powder containing drug, L-HPC having a hydroxypropoxyl group of about 4-20%, and sucrose (column 1, lines 55-68, and column 3, lines 45-56). The drug can be selected from the group including benzimidazole (column 2, line 18). Makino also teaches the granules can be further coated with Eudragit® (enteric) (column 4, lines 15-29). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation select L-HPC having a content of the hydroxypropoxyl group from about 4 in view of the teaching of Makino with the expectation of providing a faster disintegrating dosage form, because the references teach the desirability to obtain a rapidly disintegrate tablet having superior compressibility, hardness, and pleasant organoleptic sensation in the mount of the patient.

Response to Arguments

Applicant's arguments filed 04/13/06 have been fully considered but they are not persuasive.

Applicant argues that the '981 reference (Khankari) is not proper art in view of applicant's priority date of July 28, 1998 based upon the related Japanese patent

application. However, it is noted that Khankari has a filing date of April 09, 1998, which is earlier than the Japanese foreign priority date that applicant relied upon. Accordingly, the 103(a) rejections over Depui et al. in view of Khankari et al. are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-

0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615